APR 2 0 2001

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 607.92

The assigned 510(k) number is: K010313

Submitter's Name: George M. Plummer
Dade Behring, Inc.
Building 500, Mailbox 514
P.O. Box 6101
Newark, De 19714-6101
Phone: (302) 631-9798
Fax: (302) 631-6299

Date of Preparation: 1/31/2001

Device Name: Dimension® CTNI Flex® reagent cartridge

Classification Name: Immunoassay Method, Troponin Subunit

Predicate Device: Stratus® Cardiac Troponin-I Fluorometric Enzyme Immunoassay

Device Description:
The CTNI method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module is a one-step enzyme immunoassay based on the "sandwich" principle. Samples is incubated with chromium dioxide particles (CrO_2), coated with a monoclonal antibody specific for cardiac troponin-I, and a conjugate reagent [alkaline phosphatase (ALP) labeled monoclonal antibody specific for cardiac troponin-I] to form a particle/cardiac troponin-I/conjugate sandwich. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound ALP initiates an amplification cascade. ALP dephosphorylates synthetic flavin adenine dinucleotide phosphate (FADP) to produce FAD. FAD binds to APO D-amino acid oxidase and converts it to active holo D-amino acid oxidase. Each molecule of holo D-amino acid oxidase then produces multiple molecules of hydrogen peroxide (H_2O_2), which in the presence of horseradish peroxidase (HRP), converts 3,5-dicholor-2-hydroxylbenzenesulfonic acid (DCHBS) and 4-aminoantipyrine (4AAP) to a colored product that absorbs at 510nm. The color measured is directly proportional to the concentration of cardiac troponin-I present in the patient sample.

Intended Use:

The CTNI method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic test intended to quantitatively measure cardiac troponin-I levels in serum and heparinized plasma to aid in the diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

Comparison to Predicate Device:

Item	Revised Dimension® CTNI Flex® reagent cartridge	Stratus® CS Cardiac Troponin-I (CCTNI) TestPak
Technology	Sandwich format monoclonal antibody immunoassay	Sandwich format monoclonal antibody immunoassay
Monoclonal Antibodies • Tag • Capture	 • 2B1.9 • 2F6.6	 • 2B1.9 • 2F6.6
Detection	Colorimetric rate measurement at 510nm and 700nm	Front surface fluorometry measurement
Solid Support	Chrome	Glass fiber paper
Specimen Type	Serum or heparinized plasma	Heparinized plasma
Sample Size	50uL	100uL
Intended Use	For the quantitative determination of cardiac troponin-I levels in serum and heparinized plasma	For the quantitative determination of cardiac troponin-I levels in heparinized plasma
Indications for Use	To aid in diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality	To aid in diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality
Assay Range	0-40ng/mL	0-50ng/mL

Comments on Substantial Equivalence:
Method correlation between the Stratus® CS and Dimension® Cardiac Troponin I methods was evaluated with 64 heparinized patient samples ranging from 0.02 to 24.66ng/mL. These samples provided a correlation coefficient of 0.98, a slope of 1.02, and an intercept of –0.45ng/mL

Serum vs. plasma correlation was evaluated by testing matched serum and plasma patient samples with both the current and revised CTNI method on the Dimension® system. Test results with 36 clinical patient samples ranging from 0.03 to 38.97 ng/mL gave a correlation coefficient of 1.00, a slope of 1.07, and an intercept of –0.04ng/mL.

Conclusion:
The revised CTNI method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module is substantially equivalent in principle and performance to the Stratus® CS Cardiac Troponin-I (CCTNI) TestPak based on the split sample comparison summarized in the previous section, Comments on Substantial Equivalence.

George M. Plummer
Quality Assurance and
Compliance Manager
Date: 1/31/2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 0 2001

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: 510(k) NUMBER: K010313
Trade/Device Name: Dimension® CTNI Flex® Reagent Cartridge
Regulation Number: 862.1215
Regulatory Class: II
Product Code: MMI
Dated: April 2, 2001
Received: April 5, 2001

Dear Mr. Vaught:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

K010313

Device Name: Dimension® CTNI Flex® reagent cartridge

Indications for Use:
The CTNI method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic test intended to quantitatively measure cardiac troponin-I levels in serum and heparinized plasma to aid in the diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

George M. Plummer
Quality Assurance and
Compliance Manager
January 31, 2001

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010313

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CRF 801.109)

(Optional Format 1-2-96)